MAY 2 0 2002

K020849

510(k) Summary
IRIDEX® Corporation
Apex® 800 Dermatology Laser System

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

IRIDEX Corporation
1212 Terra Bella Avenue
Mountain View, CA 94043

Contact Person: John D'Angelo
(650) 962-8848 ext. 3905

Date Prepared: March 11, 2002

Device Information

Trade Name:	Apex 800 Dermatology Laser System
Classification Name:	Laser Instrument, Surgical, Powered
CFR Section:	878.4810.
Product Code:	GEX.

Equivalent Devices

The Apex 800 Laser System is substantially equivalent in intended use and technological characteristics to other currently legally marketed dermatology laser devices including the IRIDERM Apex 800 (K992298), the Coherent LightSheer (K003614), the Cynosure Apogee – TKS and Photogenica DL Laser Systems (K992757 and K010005) and the Palomar SLP 1000 (K013028).

Device Description

The Apex 800 is a semiconductor diode laser system that delivers pulsed infrared 800 nm laser light.

Intended Use

The IRIDEX Apex 800 Laser System is indicated for hair removal and permanent hair reduction on all skin types (Fitzpatrick skin types I-VI), including tanned skin; for the treatment of pseudofolliculitis barbae; for the treatment of vascular lesions including angiomas, hemangiomas, telangiectasia; for the treatment of leg veins; and for the treatment of benign pigmented lesions.

Conclusion

The Apex 800 is substantially equivalent to the identified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 0 2002

Mr. John D'Angelo
Vice President, Regulatory Affairs
and Quality Assurance
IRIDEX Corporation
1212 Terra Bella Avenue
Mountain View, CA 94043

Re: K020849
Trade/Device Name: Apex 800 Dermatology Laser System
Regulation Number: 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: March 11, 2002
Received: March 15, 2002

Dear Mr. D'Angelo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): ~~Pending~~ K020849

Device Name: Apex® 800 Dermatology Laser System

Indications For Use:

The IRIDEX® Apex 800 Laser System is indicated for hair removal and permanent hair reduction on all skin types (Fitzpatrick skin types I-VI), including tanned skin; for the treatment of pseudofolliculitis barbae; for the treatment of vascular lesions including angiomas, hemangiomas, telangiectasia; for the treatment of leg veins; and for the treatment of benign pigmented lesions.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K020849

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)